

66793 U.S. PTO



08/18/97

REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for U.S. Patent
No.: 5,498,240

Issued September 10, 1996

Inventors: Bagaoisan, *et al.*

Serial No.: 08/843,711

For: **INTRAVASCULAR CATHETER
WITH A REPLACEABLE SHAFT
SECTION**

Filed: April 16, 1997

Docket No.: 22965.2111

Examiner: to be assigned

Group Art Unit 3306

DECLARATION OF EDWARD J. LYNCH PURSUANT TO 37 C.F.R. §1.175

The Assistant Commissioner of Patents
Box Reissue
The United States Patent and Trademark Office
Washington, DC 20231

Dear Sir:

I, Edward J. Lynch, depose and say that:

1. I am a member of the State Bar of California and I am registered to
practice before the United States Patent and Trademark Office (Reg. No. 24,422).

2. I have specialized in the practice of patent law since 1968.

3. I prepared and prosecuted the application Serial No. 08/250,785 ('785 application) which issued as U.S. Patent 5,498,240 ('240 patent).

4. During the first quarter of 1997 I undertook a review of the '240 patent and, as a result of my review, I concluded that the '240 patent was inoperative or invalid by reason of the patentees claiming less than they had a right to claim as discussed in more detail below. During the prosecution of the '785 application before the U.S. Patent and Trademark Office, I did not appreciate the breadth of the invention disclosed. More specifically, I did not appreciate that claims 1, 6 and 12 of the '240 patent were unduly limited in several aspects, or that claim 12 lacked certain desirable clarifying language which would effectively broaden the scope of that claim.

5. The unduly limiting language in claim 1 of the '240 patent included the following:

- In Col. 5, line 55, the expression "with an exchangeable shaft section".

6. New claim 28, included with the present reissue application, does not have the unduly limiting language of claim 1 referred to above and has clarifying language and therefore is broader than claim 1 of the '240 patent in one or more aspects. The broadened aspects of new claim 28 include:

- The claim requires the catheter be adapted for introduction into the vascular system over a guidewire and withdrawal from the vascular system over the guidewire.

7. The clarifying aspects of new claim 28 which were lacking in claim 1 include

- The claim requires restraining the guidewire during removal of the proximal or distal shaft section.

8. The unduly limiting language in claim 6 of the '240 patent included the following:

- In Col. 6, line 25, the expression "dilatation catheter with an exchangeable shaft section".

9. New claim 25, included with the present reissue application, and claim 30 presented by preliminary amendment, do not have the unduly limiting language of claim 6 referred to above and therefore are broader than claim 6 of the '240 patent in one or more aspects. The broadened aspects of new claim 25 and claim 30 include:

- The claims are directed to an intravascular catheter, and not to a dilatation catheter as in claim 6.

- The claims require a plurality of segments having connectors which are secured together in end-to-end relations to form said catheter, and not a catheter with an exchangeable shaft section comprising a proximal shaft section releasably connectable to a distal shaft section as in claim 6.

10. The unduly limiting language in claim 12 of the '240 patent included the following:

- In Col. 7, line 24, the expression "of treating a patient's body lumen,".
- In line 37, the step of "withdrawing the intraluminal catheter from the patient".
- In line 39, the step of "removing the replaceable distal shaft section".
- In line 41, the step of "connecting a replacement distal shaft section".

11. New claim 24, included with the present reissue application, and new claim 29 presented by preliminary amendment, do not have the unduly limiting language of claim 12 referred to above and therefore are broader than claim 12 of the '240 patent in one or more aspects. The broadened aspects of new claim 24 and claim 29 include:

- The claims are directed to a method of performing a medical procedure, not to a method of treating a patient's body lumen as is claim 12.
- The claims require first and second catheter sections, and not a replaceable distal shaft section as in claim 12.

- The claims require pulling the portion of the second shaft section to withdraw at least part of the catheter shaft from the patient, and not withdrawing the intraluminal catheter from the patient as in claim 12
- The claims require disengaging one of the catheter shaft section from the other catheter shaft section, and not removing the replaceable distal shaft section as in claim 12.
- The claims do not require connecting a replacement distal shaft section to the proximal shaft section as in claim 12.

12. New claim 26, included with the present reissue application also does not have the unduly limiting claim language of claim 12 referred to above and has clarifying language and therefore is broader than claim 12 of the '240 patent in one or more aspects. The broadened aspects of new claim 26 include:

- The claim is directed to a method of removing an intravascular catheter from a patient's vascular system, and not a method of treating a patient's body lumen as in claim 12.
- The claim does not require a replaceable distal shaft section as in claim 12
- The claim requires removing a proximally mounted section of said catheter, and not removing the replaceable distal shaft section.
- The claim does not require connecting a replacement distal shaft section to the proximal shaft section as in claim 12.

13. The clarifying aspects of new claim 26 which were lacking in claim 12 include:

- The claim requires grasping said catheter and guidewire and withdrawing the catheter while restraining the guidewire.
- The claim requires sliding said catheter section off of the guidewire while grasping the guidewire to prevent retracting movement.

14. New claim 27, included with the present reissue application also does not have the unduly limiting claim language of claim 12 referred to above and has clarifying language and therefore is broader than claim 12 of the '240 patent in one or more aspects. The broadened aspects of new claim 27 include:

- The claim is directed to a method of withdrawing a catheter from a patient's vascular system, and not a method of treating a patient's body lumen as in claim 12.
- The claim requires at least a distal section and proximal section releasably connected, and not a replaceable distal shaft section as in claim 12.
- The claim requires withdrawing said catheter from said vascular system by first removing said proximal section and then said distal section, and not withdrawing the intraluminal catheter from the patient and then removing the replaceable distal shaft section.

- The claim does not require connecting a replacement distal shaft section.

15. The clarifying aspects of new claim 27 which were lacking in claim 12 include:

- The claim requires advancing a catheter over a guidewire, and restraining said guidewire while removing the shaft sections.

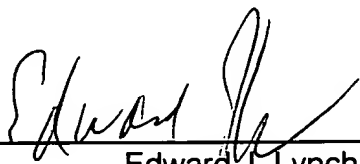
16. The above instances of unduly limiting language in claims 1, 6 and 12 of the '240 patent were errors because the applicants claimed less than they had the right to claim and I became aware of these errors in my review of the '240 patent in the first quarter of 1997.

17. These errors occurred during the preparation and prosecution of the '785 application, within a period of from some time before the filing date of May 27, 1994 to September 10, 1996, the date the '240 patent issued. These errors arose without deceptive intention.

18. Applicants acknowledge the duty to disclose to the Patent Office all information known to the applicants to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any reissue patent issued thereon.

Executed this 14th day of August, 1997 at Palo Alto, California.



Edward J. Lynch

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